

### **ELECTION**

At page 2 of Paper No. 7, restriction is required to one of the inventions defined by Groups I-XVIII. Applicants respectfully traverse the restriction requirement and respectfully request reconsideration and modification of the restriction requirement for the reasons set forth below. Pursuant to 37 C.F.R. § 1.143, Applicants provisionally elect the claims of Group III (claims 1-10 and 12) drawn to a composition comprising  $\beta$  human chorionic gonadotropin ( $\beta$ hCG) fusion protein wherein the recombinant fusion protein comprises a  $\beta$ hCG protein, fragment or analog joined to a  $\beta$ -galactosidase protein or fragment thereof, chitosan-based adjuvant and further comprises the amino acid sequence of SEQ ID NO: 2.

### **REMARKS**

Claims 1-58 are pending in this application. Applicants have provisionally elected claims 1-10 and 12 for further prosecution on the merits.

#### **A. Response and Traversal of the Restriction Requirement**

At page 2 of Paper No. 7, restriction is required to one of the inventions defined by Groups I-XVIII. At page 6 of Paper No. 7, the Examiner characterizes EP 0368253 ("Partain") as teaching a composition comprising  $\beta$  human chorionic gonadotropin protein ( $\beta$ hCG) and chitosan-based adjuvant. The Examiner alleges that claims 1-58 do not contribute a special technical feature when viewed over Partain because claims 1-58 do not have a single general inventive concept and, therefore, lack unity of invention. On the basis of the alleged lack of unity of invention, the Examiner requires restriction of further prosecution on the merits to one of the inventions defined by Groups I-XVIII. Each of the inventions defined by Groups I-XVIII is directed to a  $\beta$ hCG protein comprising either the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4. Applicants respectfully note that both SEQ ID NO:2 and SEQ ID NO:4 define the amino acid sequence of a fusion protein comprising a fragment of  $\beta$ hCG (amino acids 22-165). See page 12, line 28 to page 13, line 12 (construction of vector with insert coding for SEQ ID NO:2) and page 15, lines 6-14 (construction of vector with insert coding for SEQ ID NO:4). Applicants respectfully traverse the restriction requirement. Applicants respectfully submit the Examiner has impermissibly limited the electable inventions to particular species of fragments of

a  $\beta$ hCG fusion protein. Applicants respectfully submit that the Examiner has incorrectly determined the special technical feature of claims 1-58, and in doing so, has impermissibly defined the electable inventions of Groups I-XVIII.

Claims 1-58 are directed to the genus of  $\beta$  human chorionic gonadotropin protein ( $\beta$ hCG) and/or fusions, fragments or analogs thereof, and a chitosan-based adjuvant. Individual species of the genus of claims 1-58 are the following:

- 1)  $\beta$  human chorionic gonadotropin protein ( $\beta$ hCG), and a chitosan-based adjuvant;
- 2) **fragments** of  $\beta$  human chorionic gonadotropin protein ( $\beta$ hCG), and a chitosan-based adjuvant;
- 3) **analog**s of  $\beta$  human chorionic gonadotropin protein ( $\beta$ hCG), and a chitosan-based adjuvant.
- 4) **fusion proteins** comprising  $\beta$  human chorionic gonadotropin protein ( $\beta$ hCG), and a chitosan-based adjuvant;
- 5) **fragments of fusion proteins** comprising  $\beta$  human chorionic gonadotropin protein ( $\beta$ hCG), and a chitosan-based adjuvant; and
- 6) **analog**s of **fusion proteins** comprising  $\beta$  human chorionic gonadotropin protein ( $\beta$ hCG), and a chitosan-based adjuvant.

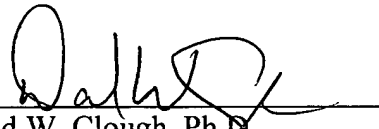
While the Examiner asserts that Partain teaches  $\beta$ hCG and a chitosan-based adjuvant (species 1), the Partain does not teach a  $\beta$ hCG fusion protein and a chitosan-based adjuvant. Applicants respectfully submit that a single general inventive concept contributing a special technical feature over the cited reference is, *inter alia*, a  $\beta$ hCG fusion protein or fragments or analogs thereof (species 4-6). In view of Examiner's failure to consider  $\beta$ hCG fusion proteins and a chitosan-based adjuvant as a single general inventive concept contributing a special technical feature over the cited prior art, Applicants respectfully request reconsideration and modification of the restriction requirement. Applicants respectfully request that the restriction requirement be modified to include compositions (claims 1-12), methods of inducing fertility (claims 13-46) and use for the manufacture of a medicament (claims 47-58) in a single electable group directed to a sub-genus of  $\beta$ hCG fusion proteins or fragments or analogs thereof and a chitosan-based adjuvant.

**CONCLUSION**

In view of the above remarks, the Applicant respectfully request reconsideration and modification of the restriction requirement. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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